FOR ARGUMENT

No. 78-605

In the Supreme Court of the United States

OCTOBER TERM, 1978

UNITED STATES OF AMERICA, et al.,

Petitioners,

vs.

GLEN L. RUTHERFORD, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Tenth Circuit

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BRIEF, AMICUS CURIAE, IN SUPPORT OF RESPONDENTS, OF CANCER CONTROL SOCIETY

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BRIEF, AMICUS CURIAE, IN SUPPORT OF RESPONDENTS, OF CANCER CONTROL SOCIETY

The Cancer Control Society and Laetrile

The Cancer Control Society is a California not-for-profit corporation, and its membership is comprised of thousands of men and women, approximately 50% of which are either present or former cancer victims, or members of their immediate families are such. The Society publishes scientific

information from both orthodox and other sources, performs research into cancer therapies available in the U. S. and elsewhere, and maintains up-to-date information as to where cancer sufferers may seek relief, when so often ineffective conventional cancer treatment has been of no avail. Its members believe that health freedoms are inherently guaranteed to us as human beings.

The Society opposes monopoly and compulsion in matters related to cancer therapies, and its membership believes in the "freedom of choice" now, and always, exercised by American citizens as to their health, and opposes bureaucratic dictation in health matters, of any type whatsoever from Washington, D.C., or elsewhere. The Society urges that freedom encompasses the freedom of the terminally ill, members of the respondent class, and, in fact, everyone to choose between existing therapies for the treatment of cancer. The Society also believes that such choice between highly toxic and largely ineffective orthodox cancer therapies, and non-toxic therapy of treatment with Laetrile, as included in an overall "metabolic therapy" program, lies within the Constitutionally protected right of privacy, allowing members of the Respondent class, and others, to make said choice free from governmental intervention or dictation.

The Rulings of the U. S. District Court

Heretofore the U. S. District Court for the District of Oklahoma, Honorable Luther Bohanon presiding, has ruled extensively concerning the legal status of Laetrile, these rulings having followed a so-called "rule-making" proceeding of FDA, previously ordered by the U. S. Court of Appeals for the Tenth Circuit and the U. S. District Court in prior rulings.

The December, 1977 opinion of the District Court (Pet. App. 11-44A) is reported at 438 F. Supp. 1287.

The U. S. District Court ruling was, in summary:

1. That Laetrile, on October 9, 1962 (and, therefore, thereafter) was "generally recognized as safe" and met the other criteria of the 1962 "Grandfather Clause" to the Federal Food, Drug, and Cosmetic Act, and therefore is a drug proper and legal for distribution in interstate commerce.

2. That there is a Constitutional "right of privacy" which attaches to Respondent Glen Rutherford, and the others of the class action group of plaintiffs who have brought the within action, as well as to those not specifically members of that class, which bars FDA from interfering with their use of Laetrile.

The Society considers the U. S. District Court opinion and ruling in question to be well-reasoned, exhaustive and definitive in all respects, and it deems it superfluous at this point to amplify or further discuss the same. The Society adopts the ruling of said lower Court in all respects as though set forth herein in full in this amicus curiae brief.

The Society further notes to the Court that FDA herein does not seek to limit availability of Laetrile to terminal cancer patients, or even any other designated class of persons, but by the ruling it seeks from this Court would bar Laetrile to everyone, no matter what their position or condition.

If the petitioner agency is successful herein in its plea to the Court, namely that no one, not even a terminal cancer patient, may receive Laetrile in any form, thousands of patients now dependent upon Laetrile, and presently pro-

tected by the decrees of the District Court below and the 10th Circuit U. S. Court of Appeals, will be effectively left to die without the treatment they now value for their very lives.

Cancer — A National Disaster

The petitioner agency unjustifiably seeks to "gloss over", so to speak, the depressing national cancer statistics, imputing to this Court that with orthodox, or conventional, cancer therapies, we are "winning" in the battle against cancer. Therefore, according to FDA reasoning, Laetrile could not possibly be desired by anyone. Petitioner even includes in its brief (page 73) "statistics" designed to buttress this argument. However, and interestingly enough, these are not U. S. Government statistics, but gleaned from a medical journal article not substantiated in the record herein.

Whatever the case, we are losing 400,000 Americans per year from cancer, with the mortality rate steadily increasing. If present projections are taken into account, one in four Americans is doomed to die of cancer. The *cancer death rate* has more than trebled since 1900, and the median survival time (based upon approximately 219,500 cases of cancer) is only *1.7 years.* The death rate for distant or disseminated cancer cases over a five-year period is *91%.*

Small wonder that terminal cancer patients like Respondent Rutherford, and others, desire Laetrile to prolong their lives, and even help them back to health, when orthodox therapy is totally ineffectual.

Orthodox Therapy — Ineffectual and Dangerous

The Food and Drug Administration has a long history of allowing dangerous and worthless cancer drugs on the market, and its opposition to Laetrile is inexplicable under the circumstances at hand, wherein for very minor reasons, the Agency seeks to challenge the "safety" of Laetrile, as contrasted with purportedly "safe" cancer drugs already approved by the Agency. The Society trusts that this attempt to create a "double standard" as applied to Laetrile shall not be permitted by the Court.

Presumably FDA seeks to justify its approval of drugs already on the market upon the premise of a "benefit-risk" ratio, namely that the benefits are so tremendous that any "risk" is a minor consideration to be assumed by the cancer sufferer.

However, in actuality, the various cancer drugs approved previously by FDA are not beneficial and "curative", but are dangerous, even lethal and fatal, and many of them cause cancer, although designated as "anti-cancer" drugs.

Among these FDA-approved drugs are *Cytoxan,* which according to FDA-approved manufacturer's labeling can cause death, also can cause cancer, and numerous other body-destroying effects. Likewise, *Adriamycin* can cause congestive heart failure, bone marrow depression, hemorrhage and numerous other ghastly effects. *Adrucil, BICNU, CeeNU, DTIC, Mutamycin, Matulane, Mithracin, FUDR, Fluorouracil, Methotrexate,* and *Blenoxane* are other drugs FDA-approved for "safety", and are severely toxic, and/or death-causing, cancer-causing, and all of them replete with a host of other undesirable and dangerous side effects.

Not one of these drugs is represented to be "curative."[1]

Laws of the States To Be Ignored?

Petitioner's brief contains not one word as to the laws of 19 states thus far enacted and approved for use of Laetrile.

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[1] For further information on the foregoing FDA-approved drugs, see "Physicians' Desk Reference", 1979, a standard reference work for doctors, monitored by FDA as to its contents.

The nineteen States are: Alaska; Arizona; Delaware; Florida; Idaho; Illinois; Indiana; Kansas; Louisiana; Maryland; Nevada; New Hampshire; New Jersey; North Dakota; Oklahoma; Oregon; South Dakota; Texas; and Washington.[2]

The Laetrile legislation in South Dakota was approved only as of March, 1979, and additional Laetrile legislation is pending in various other States.

The petitioner agency would have the Court believe that anyone who would employ Laetrile in any capacity is perpetrating a "fraud". Are we then to believe that the legislatures of 19 states are assisting in such "fraud", or is it more reasonable to believe that, for the first time in history, a drug has proved of such value for cancer sufferers that 19 states have deemed it appropriate and necessary to note by legislation its importance, a circumstance, which, the Society believes, has never occurred in the history of the United States?

Any Compelling State Interest?

FDA argues herein that there is a "compelling state interest" which must be invoked by the Court to bar

[2] *Alaska* (See Alaska Statutes 08.64.367); *Arizona* (See A.R.S. 36-2451); *Delaware* (See Del. Code Ann. 16 Section 4901); *Florida* (See F.S.A. 458.24); *Idaho* (See Idaho Code 18-7301A); *Illinois* (See S.H.A. 56½, Section 1801); *Indiana* (See Burns Ind. St. Ann. 16-8-8-1); *Kansas* (See S.B. 505 May 8, 1978); *Louisiana* (See L.S.A.—R.S. 40:676); *Maryland* (See Ann. Code of MD, Art. 43 Sec. 133 ch. 809); *Nevada* (See Nev. Rev. St. 630.303); *New Hampshire* (See R.S.A. 329:30); *New Jersey* (See N.J.S.A. 24:6F-1); *North Dakota* (See H.B. 1214 eff. July 1, 1979); *Oklahoma* (See 63 Okl. St. Ann. Sec. 2-313); *Oregon* (See Oregon Rev. St. 689.885); *South Dakota* (Bill Number 1287 signed 3/16/79 eff. 7-1-79); *Texas* (See Vernon's Ann. Civ. St. 71 art. 4476-5a.); *Washington* (See R.C.W.A. 70.54.130).

Laetrile to everyone. The Society urges that this is simply not so.

John Stuart Mill, in his classic work, *On Liberty*, gives substance to the concept of "compelling state interest" when he asserts: ". . . one very simple principle, as entitled to govern absolutely the dealings of society with the individual in the way of compulsion and control, whether the means used be physical force in the form of legal penalties, or the moral coercion of public opinion. *That principle is, that the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number, is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others.* His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise, or even right. These are good reasons for remonstrating with him, or reasoning with him, or persuading him, or entreating him, but not for compelling him, or visiting him with any evil in case he do otherwise. To justify that, the conduct from which it is desired to deter him, must be calculated to produce evil to some one else. The only part of the conduct of any one, for which he is amenable to society, is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign."

Important Constitutional Rights Involved

The Constitutional right of privacy in the case at bar, as affecting both physician and patient, has been discerned and validated by this Court in the parameters of the Bill

of Rights, and specifically within the language of the First, Fourth, Fifth, Ninth and Fourteenth Amendments to the Constitution. *Roe* v. *Wade*, 410 U.S. 113 (1973). This right has been recognized as a fundamental right guaranteed to the individual. *Griswold* v. *Connecticut*, 381 U.S. 479 (1965). One noted authority has described the central theme of the right of privacy as the individual freedom to make knowing choices as long as they do not adversely affect others. Beardsley, *Privacy: Autonomy and Selective Disclosure*, in Privacy, Nomos XIII, at 56 (1971).

The aspect of the right of privacy relating to personal autonomy is derived from the common law interest defined as the "right to be let alone." In his oft-quoted dissent, Justice Brandeis in *Olmstead* v. *United States*, 277 U.S. 438, 478 (1928), overruled in *Katz* v. *United States*, 389 U.S. 347, 352-53 (1967), stated:

> "The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation . . ."

This Court's modern privacy rulings have been strongly solicitous of individual choice in highly personal circumstances. See, e.g., *Griswold* v. *Connecticut, supra*, (1965); *Loving* v. *Virginia*, 388 U.S. 1 (1967); *Eisenstadt* v. *Baird*, 465 U.S. 438 (1972); *Roe* v. *Wade*, 410 U.S. 113 (1973);

Doe v. *Bolton*, 410 U.S. 179 (1973). Respondents are before this Court in the context of a similar highly personal situation. A denial of the right to choose Laetrile in the treatment of their *incurable disease* is, in what is a clear absence of a compelling interest on the part of petitioners, an unconstitutional denial of their fundamental right of privacy.

This Court established the right of a patient to choose an unapproved method of treatment in *Roe* v. *Wade* and *Doe* v. *Bolton, supra*. By acknowledging the right to undergo an unauthorized medical procedure, these cases went beyond the mere recognition of the patient's right to decline treatment or to choose a particular unapproved method of treatment.

Respondents' right to refuse medical treatment is incontrovertible. Should they decide to forego conventional treatments, as Glen Rutherford chose to forego a colostomy, do they not possess a further right to enlist such nontoxic treatments, however unconventional or distasteful to FDA they must be, as they may find to be of comfort? How can the informed cancer-ridden patient, who faces virtually certain death, be limited in choice of treatment administered by a state licensed physician to only Federally sanctioned alternatives?

CONCLUSION

Man has gone through many stages in his search for health. He has tried many approaches. Many of these have proved to be blind alleys. He has learned bits and pieces. Some of what he has thought he has learned has proved not to be so. He once bled people and used leeches. He has since time immemorial experimented with herbs and foods. He has but recently begun to experiment with chemical drugs. In all of these attempts he has made what he

thought was progress. Sometimes there was real progress. Often, time showed that he has had to retract.

The Society does not claim that "orthodox" allopathic medicine has not made discoveries and has not experimented through the extensive use of drugs and surgery. But the Society does urge that conventional allopathic medicine and FDA have not yet cornered the market on truth.

The basic issues in this cause, despite any technicalities of statutes, or otherwise, reduce to a very simple circumstance:

1. When the State licenses a Doctor to treat the sick, by any and all means whatsoever, can he use his best judgment and discretion for the treatment and welfare of his patient, employing Laetrile or other therapies?

2. Or, does a bureaucratic instrumentality unaware of the needs of the patient or the condition of the patient dictate what the physician and patient shall do, superimposing State-dictated medicine?

Permitting one group to become a state-endowed monopoly is as dangerous in the healing arts as it is in economics or in political thought, perhaps more so, for here we are dealing with life itself.

Unfortunately man can be jealous of the known and reluctant to even consider what is new or different. History has shown that men of medicine and bureaucrats can be as narrow and uncompromising as other men. History has shown that many discoveries that we now consider significant were rejected by the "orthodox" and their discoveries hounded. History contains many examples to prove this point. Two late and distinguished Senators, Lister Hill of

Alabama and Paul Douglas of Illinois, had occasion to discuss this very matter on the floor of the United States Senate (109 Con. Rec. 14499):

> Mr. Douglas. Is it not true that Joseph Lister was nearly driven out of the medical profession by the British Medical Association because he said that surgery which was not antiseptic gave rise to infections and caused great mortality among the patients?
>
> Mr. Hill. He was subjected to many attacks.
>
> Mr. Douglas. By the British Medical Association?
>
> Mr. Hill: By men prominent in that association.
>
> Mr. Douglas. Is it not true that Lister was merely following the teachings of the great French physiologist, Louis Pasteur, who discovered the germ theory of disease?
>
> Mr. Hill. He applied the discoveries of Pasteur to surgery.
>
> Mr. Douglas. Is it not true that Pasteur was nearly driven from his chair at the University of Paris by the doctors and physiologists of France?
>
> Mr. Hill. That is correct.
>
> Mr. Douglas. Looking back in history, is it not also true that Semmelweis—and in our country Oliver Wendell Holmes, Sr.—who discovered the cause of puerperal fever, resulting in death of women in childbirth—the cause being the dirty hands of doctors—was nearly driven from the profession?
>
> Mr. Hill. The truth is that poor Semmelweis was a martyr to the cause. He died, driven and hounded to his death.
>
> Mr. Douglas. He was driven to his death by the doctors?
>
> Mr. Hill. That is true, because he insisted on washing his hands after he came out of the dissecting room, before he delivered a woman of a child.
>
> Mr. Douglas. It was thought that that was a reflection on the medical profession, who believed that their hands were always clean and could not have anything on them that would infect others.

Mr. Hill. Yes.

Mr. Douglas. Is it not also true that Dr. Jenner, who developed the theory and practice of vaccination as a preventative, also was persecuted by the medical profession?

Mr. Hill. He was. He observed that the women in Scotland who milked cows and had cowpox largely secured an immunity from smallpox. That gave him the idea and he developed the vaccine which was the first vaccine we had against a dread disease.

Mr. Douglas. Is it not true that the teachings of Lister were brought to this country by the celebrated Dr. W. W. Keen, who, after the Civil War, went to Scotland and studied under Lister and then came back to practice in Philadelphia, and who was virtually driven out of practice in Philadelphia by the medical association and was only saved by some adventurous people on the board of the Pennsylvania General Hospital?

Mr. Hill. Dr. Keen was, according to history, the first American surgeon to use Lister's methods in Philadelphia.

Mr. Douglas. As a young man, I spent an evening with Dr. W. W. Keen, who spoke of the persecution he had been subjected to by the leaders of the medical profession in the city of Philadelphia.

Mr. Hill. He was a very remarkable man. Keen's 14-volume work was almost a bible for surgery procedures.

Mr. Douglas. Is it not true that Robert Koch, developer of 606, who did work on tuberculosis, suffered from persecution by the German medical association?

Mr. Hill. He did, as William Harvey, the discoverer of the circulation of the blood, had suffered.

Mr. Douglas. So the medical profession in many instances sought to persecute and defeat the professional men who were later hailed as great discoverers?

Mr. Hill. There are a great number of instances of that kind.

Nor is an almost interminable and prohibitively-expensive "new drug" proceeding with FDA an answer. For respondents, a class composed of terminally ill cancer patients, time is all. It has assumed, by definition but not by choice, an incalculable value.

"The final consequences (of petitioner FDA's ban on Laetrile) are ultimately borne by those whose bodies are the battleground on which cancer's war is waged." 438 F. Supp. 1287, 1300 (1977). Any legal right respondents possess to use Laetrile may be of academic value if secured only at some indetermined future time. For the terminally ill, the phrase "justice delayed is justice denied" contains special significance. Respondents ask simply that this Court remember that the acquisition of Laetrile for their own consumption is, *for them,* a matter of life and death and not one rightly governed by legal niceties. Respondents further ask that this Court reflect on the indescribable nature of the injury they must nevertheless attempt to describe, if they are to prevail here. This injury is clearly more than minimal or trivial; it is unconstitutional.

Respectfully submitted,

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